Adopted	Rejected

COMMITTEE REPORT

YES: 7
NO: 0

MR. SPEAKER:

Your Committee on ***Public Health*** *, to which was referred House Bill 1382 , has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill* ***be amended*** *as follows:*

Page 1, line 9, delete "or another serious or life threatening disease".

Page 2, line 9, delete "or other serious or" and insert "**; and**

(2) that is approved or funded by one (1) of the following:

(A) A National Institutes of Health institute.

(B) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.

(C) The federal Food and Drug Administration.

(D) The United States Department of Veterans Affairs.

(E) The United States Department of Defense.

(F) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for

Protection from Research Risks as provided in 45 CFR 46.103.

(G) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.".

Page 2, delete lines 10 through 31.

Page 3, delete lines 12 through 15, begin a new paragraph and insert:

"**(f) A state employee plan that provides coverage for basic health care services may not exclude coverage for routine care costs that are incurred in the course of a clinical trial if the plan would provide coverage for the same routine care costs not incurred in a clinical trial.**

(g) The coverage that may not be excluded under this section is subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the state employee plan, including treatment rendered by participating and nonparticipating providers.

(h) This section does not require the state employee plan to offer coverage for clinical trial services rendered by a participating provider under the state employee plan.

(i) This section does not prohibit the state employee plan from offering coverage for clinical trial services by a participating provider.

(j) This section does not require reimbursement for services that are performed in a clinical trial by a nonparticipating provider at the same rate as those performed by a participating provider.

(k) Under a patient informed consent document, no party is liable for damages associated with the treatment provided during any phase of the clinical trial.

(l) This section does not create any private right or cause of action for or on behalf of any new patient against a party that issues the state employee plan.".

Page 3, line 24, delete "or another serious or life threatening disease".

Page 3, line 41, delete "or other serious or" and insert "**; and**".

Page 3, delete line 42.

Page 4, delete lines 1 through 21, begin a new line block indented and insert:

"(2) that is approved or funded by one (1) of the following:

(A) A National Institutes of Health institute.

(B) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.

(C) The federal Food and Drug Administration.

(D) The United States Department of Veterans Affairs.

(E) The United States Department of Defense.

(F) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.

(G) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.".

Page 4, delete lines 36 through 38, begin a new paragraph and insert:

"(d) The Medicaid program may not exclude coverage for routine care costs that are incurred in the course of a clinical trial if the program would provide coverage for the same routine care costs not incurred in a clinical trial.

(e) The coverage that may not be excluded under this section is subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the Medicaid program, including treatment rendered by participating and nonparticipating providers.

(f) This section does not require the Medicaid program to offer coverage for clinical trial services rendered by a participating provider under the Medicaid program.

(g) This section does not prohibit the Medicaid program from offering coverage for clinical trial services by a participating provider.

(h) This section does not require reimbursement for services that are performed in a clinical trial by a nonparticipating provider at the same rate as those performed by a participating provider.

(i) Under a patient informed consent document, no party is liable for damages associated with the treatment provided during

any phase of the clinical trial.

(j) This section does not create any private right or cause of action for or on behalf of any new patient against the state.".

Page 4, line 39, delete "(e)" and insert "**(k)**".

Page 5, line 10, delete "or another serious or life threatening disease".

Page 5, line 27, delete "or other serious or" and insert "**; and**".

Page 5, delete lines 28 through 42, begin a new line block indented and insert:

"**(2) that is approved or funded by one (1) of the following:**

(A) A National Institutes of Health institute.

(B) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.

(C) The federal Food and Drug Administration.

(D) The United States Department of Veterans Affairs.

(E) The United States Department of Defense.

(F) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.

(G) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.".

Page 6, delete lines 1 through 7.

Page 6, delete lines 32 through 42, begin a new line block indented and insert:

"**(1) The health care service, item, or investigational drug that is the subject of the clinical trial.**

(2) Any treatment modality that is not part of the usual and customary standard of care required to administer or support the health care service, item, or investigational drug that is the subject of the clinical trial.

(3) Any health care service, item, or drug provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient.

(4) An investigational drug or device that has not been approved for market by the federal Food and Drug

Administration.

(5) Transportation, lodging, food, or other expenses for the patient or a family member or companion of the patient that are associated with travel to or from a facility providing the clinical trial.

(6) A service, item, or drug that is provided by a clinical trial sponsor free of charge for any new patient.

(7) A service, item, or drug that is eligible for reimbursement from a source other than a covered individual's policy of accident and sickness insurance, including the sponsor of the clinical trial.".

Page 7, delete lines 1 through 2, begin a new paragraph and insert:

"**Sec. 6. (a) A policy of accident and sickness insurance may not exclude coverage for routine care costs that are incurred in the course of a clinical trial if the policy of accident and sickness insurance would provide coverage for the same routine care costs not incurred in a clinical trial.**

(b) The coverage that may not be excluded under this section is subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the policy of accident and sickness insurance, including treatment rendered by participating and nonparticipating providers.

(c) This section does not require an insurer to offer coverage for clinical trial services rendered by a participating provider under a policy of accident and sickness insurance.

(d) This section does not prohibit an insurer from offering coverage for clinical trial services by a participating provider.

(e) This section does not require reimbursement for services that are performed in a clinical trial by a nonparticipating provider at the same rate as those performed by a participating provider.

Sec. 7. (a) Under a patient informed consent document, no party is liable for damages associated with the treatment provided during any phase of the clinical trial.

(b) This section does not create any private right or cause of action for or on behalf of any new patient against an insurer that issues a policy of accident and sickness insurance.".

Page 7, line 11, delete "or another serious or life threatening

disease".

Page 7, line 28, delete "or other serious or" and insert "**; and**".

Page 7, delete lines 29 through 42, begin a new line block indented and insert:

"**(2) that is approved or funded by one (1) of the following:**

(A) A National Institutes of Health institute.

(B) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.

(C) The federal Food and Drug Administration.

(D) The United States Department of Veterans Affairs.

(E) The United States Department of Defense.

(F) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.

(G) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.".

Page 8, delete lines 23 through 26, begin a new paragraph and insert:

"**(d) An individual or a group contract that provides for basic health care services may not exclude coverage for routine care costs that are incurred in the course of a clinical trial if the contract would provide coverage for the same routine care costs not incurred in a clinical trial.**

(e) The coverage that may not be excluded under this section is subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the individual or a group contract, including treatment rendered by participating and nonparticipating providers.

(f) This section does not require a health maintenance organization to offer coverage for clinical trial services rendered by a participating provider under an individual or a group contract.

(g) This section does not prohibit a health maintenance organization from offering coverage for clinical trial services by a participating provider.

(h) This section does not require reimbursement for services that are performed in a clinical trial by a nonparticipating provider at the same rate as those performed by a participating provider.

(i) Under a patient informed consent document, no party is liable for damages associated with the treatment provided during any phase of the clinical trial.

(j) This section does not create any private right or cause of action for or on behalf of any new patient against a health maintenance organization that issues an individual or a group contract.".

(Reference is to HB 1382 as introduced.)

and when so amended that said bill do pass.

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Representative Brown C